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EDITORIAL

Value of Registries for EVAR

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There is no doubt we live in the era of evidence-based medicine. The call for evidence in any part of medical practice is nowadays stronger than ever. In contrast, however, to what happened with carotid endarterectomy, the rapid increase in the performance of which followed the publication of the randomised trials, the endovascular revolution in the treatment of abdominal aortic aneurysms (AAAs) has preceded the publication of the results of the EVAR and the DREAM trials.[1–5] The support and feedback for this revolution have been provided, to a large extent, by large-scale multicenter registries, the data of which have proved to be invaluable in various aspects.

First of all, registries have been well ahead of randomised trials due to their ability to collect data quickly and efficiently. With more than 7000 patients entered by the end of 2004, EUROSTAR represents the largest registry of EVAR today,[6–9] with the RETA registry following with an also impressive number of 1823 endovascular procedures.[10,11] In comparison, the EVAR trial 1 included 543 patients in its endovascular arm[1,4] and DREAM 173.[2,5] The large number of patients in registries has enabled numerous secondary analyses, while trials are not sufficiently powered to allow ad hoc comparisons between subgroups, e.g. comparisons between endovascular aneurysm repair (EVAR) and open repair in patients with inflammatory aneurysms, identification of the risk factors for early or late conversion etc.

It should also be noted that registries can give a more complete picture of the patient population to be treated as well as of the range of methods and materials that may be employed since they have no restrictions posed by a trial protocol. Similarly, the reported results are more realistic as they are obtained in a cross-section of clinical institutions with various degrees of experience, working under routine conditions. Notably, only experienced surgical teams were invited by the DREAM and the EVAR trials, i.e. centres which had done at least 5 or 20 EVAR procedures, respectively,[1,2] whereas EUROSTAR included 135 centres, some of which even reported their first endovascular case.

Another useful application of registries is that the information obtained from them has assisted clinical investigators in designing randomised trials. Indeed, registries have been the source of questions clinical trials engaged to answer convincingly. Since the late 1990s, registries have pointed out the low perioperative mortality of EVAR in patients considered fit for open surgery (2.3–4% for patients in ASA I–III categories),[6,10] the considerable mortality in unfit patients (12.5–18% for patients in ASA IV–V categories)[6,10] as well as the problems of durability and long-term efficacy of EVAR (3% risk of late failure per year with the use of first and second-generation devices).[7] EVAR trial 1 and DREAM have recently confirmed that EVAR reduces the 30-day operative mortality in fit patients by two thirds compared with open repair,[1,2] while the EVAR trial 2 has demonstrated that EVAR does not improve survival over no intervention in patients already unfit for open repair of their aneurysm.[3] The mid-term efficacy of EVAR is still a matter of debate.[4,5]

Registries have also made some important contributions to the evolution of endovascular devices. At the time when most surgeons were unwilling to report bad results with EVAR, registries pointed out the specific problems encountered during follow-up.[5,7] Graft migration was identified and led to the manufacture of stent-grafts with improved fixation mechanisms. Graft kinking resulting from contraction of the sac in its longitudinal dimension was also reported, leading to the construction of stent-grafts with increased kink resistance. Fabric tear, hook fracture, limb disarticulation and suture breakage were also

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recorded and subsequently compensated for by better and stronger graft designs. EUROSTAR has recently verified that the use of current devices has improved the mid-term outcome of EVAR, halving the need for secondary transfemoral intervention and significantly reducing conversion to open repair and aneurysm-related death.[8]

Another potential application of registries, though not yet exploited, is that they can serve as an audit tool, monitoring the degree to which vascular surgeons are managing AAAs in accordance with the principles of best clinical practice. Direct comparisons between the morbidity and mortality of individual surgeons may enable these surgeons to modify their practice patterns. Similarly, data derived from international registries may be used by health care administrators and lead to changes in national health priorities and strategies with regard to AAA repair. For example, an important lesson learnt by the EUROSTAR registry is that specialist teams with a high level of experience in EVAR encounter lower mortality rates and fewer adverse events leading to secondary interventions.[9] Interestingly, the threshold of procedures needed to minimise complications is very high in the case of EVAR, maybe higher than 90 patients. Therefore, EVAR should be centralised in units specialising in the technique and with a sufficient number of operations annually to optimise the results.

The educational function of registries should also be underscored. For rapidly evolving techniques, such as EVAR, the information found in textbooks is already out of date by the time these books reach the shelves. Therefore, not only for students and residents, but also for vascular specialists, registries can serve as an excellent tool for continuous medical education, providing a wealth of up-to-date clinical information.

Of course, several limitations and shortcomings of registries should be acknowledged: selection bias due to the voluntary nature of the registry; participation only of enthusiastic, and thus more dedicated, surgical teams; incomplete reporting; lack of a representative control group to allow direct comparisons with open surgery; and in addition to these drawbacks, registries heavily subsidized by the industry are lacking objectivity and are not included in the levels of evidence list.[12] On the other hand, registry data have proved to be valid, truly reflecting a representative cross-section of patients, methods and hospitals. Information derived from registries is therefore invaluable for the surgeon, the resident, the researcher, the industry as well as the health care administrators.

It is therefore, imperative that the registries be conducted either by national authorities or at least under the guidance of well-respected scientific bodies such as the European Society for Vascular Surgery (ESVS). Owing to the heavy financial demands of conducting large-scale registries, financial support should be requested upon explaining to the authorities that the existence of a well-structured and well-operated registry on a European level, for such issues as endovascular treatment of aneurysms, is to the benefit of the patients, the scientific community as a whole and finally to the tax-payer.

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